Dimensional and flow properties of the EX-PRESS® Glaucoma Drainage Device

Richard M H Lee [1, 2], Amir Samsudin [1, 2, 3, 4], Yann Bouremel [1, 2, 4], Steve Brocchini [1, 2, 5], Peng Tee Khaw [1, 2]

[1] NIHR Biomedical Research Centre at Moorfields Eye Hospital NHS Foundation Trust, London, United Kingdom

[2] UCL Institute of Ophthalmology, London, United Kingdom

[3] Department of Ophthalmology, University of Malaya, Kuala Lumpur, Malaysia

[4] UCL Department of Mechanical Engineering, London, United Kingdom

[5] UCL School of Pharmacy, London, United Kingdom

Word Count

530

Grant Information

Supported by the Ministry of Higher Education, Malaysia; the NIHR Biomedical Research Centre at Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology, Moorfields Special Trustees, the Helen Hamlyn Trust (in memory of Paul Hamlyn), Fight for Sight and Freemasons Grand Charity, UK.

Disclosure

P.T.K. has been on advisory boards for Pfizer, Bausch and Lomb, Alcon, and Teva Pharmaceuticals. All other authors declare no conflict of interest.

Dear Editor,

We read with interest an article by Sheybani *et al.* (1) demonstrating the assessment of fluid dynamics and flow control between the XEN 45 micro-fistula implant, the EX-PRESS® implant (Alcon Laboratories, Inc., Fort Worth, TX, USA) and silicone tubing from a Baerveldt implant (Abbott Medical Optics, Abbott Park, IL, USA). The authors demonstrated that the Hagen-Poiseuille equation can be used to calculate the required dimensions of a tube that would prevent hypotony at average aqueous humour production and that the EX-PRESS® device, when placed without a sclera flap, results in hypotony.

It is described in the article that the EX-PRESS® device has an opening of 200μm in inner diameter that tapers to a 50μm inner lumen. Our group have previously reported our evaluation of the EX-PRESS® device. (2) There are two device models available, the P50 and the P200, with advertised 50μm and 200μm luminal internal diameters (ID) respectively. Esterman *et al.* (3) previously reported that the resistance to the flow with the EX-PRESS® device would decrease by 256 times if the luminal diameter were increased by 4 times, as expected from the Hagen-Poiseuille equation. However, they only observed a resistance value obtained with the P200 device in the order of 6 to 7 times lower than the P50 device, a finding we previously corroborated in our own study. (2)

The reduction in resistance with increased lumen ID cannot be explained with the Hagen-Poiseuille equation on the basis of their lumen ID criteria alone. On scanning electron microscopy, we observed that the internal diameter of the lumen of both the P50 and P200 were in the region of 200μm at both the subconjunctival space and anterior chamber end. We confirmed with Alcon Inc. that the P50 differs from the P200 only in having a 150μm diameter bar lying across its lumen in the middle of the device. The P50 and P200 devices also have a side orifice at the anterior chamber end of their bodies, which means they do not have a constant circular cross section. This, together with the presence of the bar lying across the lumen of the P50 device, means that Poiseuille's Law is not applicable.

Sheybani *et al* also state that the EX-PRESS® does not provide significant outflow resistance. We too observed that there were minimal differences in pressures between the EX-PRESS® device and a typical trabeculectomy. However, we observed that device implantation resulted in less variability in pressure readings and this may be due to more consistent lumen sizes with small tolerances, as

compared to making a sclerostomy with a punching device or knife. We also observed that more manipulation was required subjectively with a smaller 27 G versus 25 G needle stab on device insertion. This may result in a poorer fit around the body of the device, resulting in leakage.

We agree with Sheybani *et al*. that use of the EX-PRESS® device without a scleral flap carries significant risk of hypotony and has similar equilibrium pressures as the trabeculectomy procedure. We would highlight that the effective luminal diameter of the P50 is much larger than 50 μm and that intra-operative surgical technique may reduce tissue manipulation and therefore reduce post-operative pressure fluctuations.

Acknowledgements

Alcon Inc. (Fort Worth, TX) provided samples of the EX-PRESS® devices.

References

1. Sheybani A, Reitsamer H, Ahmed II. Fluid Dynamics of a Novel Micro-Fistula Implant for the Surgical Treatment of Glaucoma. Invest Ophthalmol Vis Sci. 2015;56(8):4789-95.

2. Samsudin A, Eames I, Brocchini S, Khaw PT. Evaluation of Dimensional and Flow Properties of EX-PRESS® Glaucoma Drainage Devices. J Glaucoma. 2015 Feb 25.

3. Estermann S, Yuttitham K, Chen JA, et al. Comparative in vitro flow study of 3 different Ex-PRESS miniature glaucoma device models. J Glaucoma. 2013;22:209–214.